PAMELA W. ADAMS, MS, RAC, CQM

SUMMARY OF QUALIFICATIONS

Scientific background and expertise, education and experience in business performance excellence tools, product development, compliance, preparation of CE marking documents, IDE, IND's and 501(k) marketing submissions, as well as development and maintenance of quality systems for QSR, ISO and MDD compliance. Experienced leader in definition and execution of strategic initiatives. Results oriented; professionalism, interpersonal skills and ability to manage multiple projects and responsibilities.

WORK EXPERIENCE

ETEX CORPORATION, INC., (Cambridge, MA)
Chief Operating Officer, January 2002 – present. Operational responsibility for design, development and commercial manufacturing operation related to calcium phosphate-based orthobiologics. Key contact for company's development and distribution partners, reflecting use of ETEX's technology for growth factor delivery, implant coatings, and other Class II/III orthopedic applications.
VP, Quality Systems and Regulatory Affairs, September 1999 - January 2002
Achieved ISO 9001, EN 46001, ISO 13485 & MDD Certification. Full responsibility for quality system compliance, product and process validation, customer complaint handling & MDR reporting, management of inspections, internal & vendor audits, vendor interface and CAPA system. Regulatory strategy for product & process changes, new Class III orthopedic, osteobiologic products and combination products; *510(k) filings, IDE annual progress reports, TPP license submissions, preparation of Design Dossier for CE marking.* Review & edit labeling and promotional material. Monitor and update Device Listing and Device Establishment Registrations; *Established company Performance Indicators & Part 11 compliance.*

MEDTRONIC, INC. (Formerly USCI Div, C.R.BARD and AVE, Inc.)
Director, Quality Assurance and Regulatory Affairs, October 1998 – May 1999
Maintain quality system compliance for Class II & III interventional cardiology product manufacturer. Coordinate regulatory submissions, determinations and compliance. Direct design development and verification testing functions, quality engineering, quality control and inspection, documentation and records control, field assurance and complaint handling, sterilization, microbiology and auditing. Senior member of extensive M & A program, including downsize, restructure and systems consolidation.

C. R. BARD, INC
Director, Quality Assurance Shared Services, May 1998 - October 1998
Led a team of internal Quality professionals in the provision of client-focused, cost effective quality services optimized to support objectives of five business operating units. Implemented contracts, pricing, structure, compensation programs, productivity improvement goals and outsourcing strategies. Invited speaker, The Conference Board, April 1999 "*Key Implementation Issues, Shared Services"*.

Program Manager, New Product Development, March 1997 - April 1998
Directed multi functional team in development of Class III medical device; managed relationships of inventors, OEM manufacturer, engineers, clinical investigators and engineers to clarify objectives, customer requirements and performance measures. Invited speaker, Regulatory Affairs Professional Society, 1997 Annual Meeting, *"Human Resource Issues for Senior Regulatory Affairs Professionals"*

Piloted Corporate Team Effectiveness Breakthrough Strategy program.
Initiated formation of Cardiology Innovation team skilled at creative problem solving. *Conducted innovation sessions, which resulted in 30 new product ideas for R & D.*

Manager, Laboratory Services, July 1991 - March 1997

Directed and implemented laboratory data integrity corrective action program, mandated during AIP. *Implemented GLPs in all Laboratories, earned recognition by third party audit team for "data integrity excellence", which resulted in the lifting of the FDA AIP within 14 months. Reduced operational costs 50%; increased client support by 25%. Reduced inspection and test costs over $1M in 1996.*

Directed multi functional team in implementation of long range business process improvement initiative based upon Baldrige criteria; *earned Level I Massachusetts Quality Award for project.* Invited speaker, Mass. Council for Quality 1997 Winners conference ,*"Self Assessment Panel"*

Led Corporate Sterilization and Laboratories Steering Committee in actions which *reduced Corporate costs over $1M in 1996.* Sponsored Sterilization and Laboratories Technology Forum attended by internal technical professionals from 17 facilities and 6 countries in 1995.

Marketed labs to Corporation; *increased client base 15% without additional personnel.*
Transformed Sterilization function from rating of "Deficient" to "Area of Proficiency".
Saved $400K in inventory costs by reducing sterilization turnaround time by up to 75%.
Reduced customer complaint investigation laboratory volume by 85% in 90 days. Selected *exemplar leader* in Corporate Management Competencies/Leadership Training initiative.

MILLIPORE CORPORATION, STERIMATICS DIVISION
Project Leader, 1988 - July 1991
Managed bacterial endotoxin assay development project. Coordinated microbiological validation for high purity water systems and sterile large volume parenteral solution production units.

E. I. DUPONT, INC (Formerly NEW ENGLAND NUCLEAR COMPANY)
Supervisor, Quality Control Microbiology, 1983 - 1986
Supervised microbiologists associated with small volume parenteral drug manufacture; ensured USP and GMP compliance. Audit and qualification of contract manufacturers and sterilization operations. *Implemented improvements saving $59K annually.*

Quality Assurance Technical Specialist, 1980 - 1983
Validation - new sterile pharmaceutical facility clean rooms, water, compressed air, aseptic processing and controlled environment systems; GMP training. Implemented environmental control/trending.

Project Leader, Reagent Development, 1979 - 1980
Microbiologist, Quality Control, 1975 - 1979
Established internal microbial taxonomy laboratory supporting environmental monitoring programs for sterile manufacturing, air and water. *Saved $50K in test costs.*

EDUCATION

HARVARD SCHOOL OF PUBLIC HEALTH
Science Masters, Microbiology, 1979

BOWLING GREEN STATE UNIVERSITY
Bachelor of Science, Major, Applied Microbiology, Minor, Chemistry, 1976

RELATED EXPERIENCE & QUALIFICATIONS

MASS EXCELLENCE, *Chairman, Board of Directors, 2001 – present; Board of Directors, 1998 - 2001*
AMERICAN SOCIETY FOR QUALITY, *Certified Quality Manager (CQM), 1998*
REGULATORY AFFAIRS CERTIFIED *(RAC), 2000*
ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION, *Board of Directors, present*